

**ATTACHMENT 2**  
**510(k) SUMMARY****APR 11 2008**

510(k) Owner: InTouch Health®  
90 Castilian Drive, Suite 200  
Goleta, CA 93117

Contact: Bill Stout  
Phone: 805-862-8686 x112  
Fax: 805-562-8663

Date Summary Prepared: 12/28/07

Device: Trade Name: Remote Presence Robotic System  
  
Common/Classification Name: Physiological signal transmitter and receiver (21 C.F.R. § 870.2910, Product Code DRG); Class II electronic stethoscope (21 C.F.R. § 870.1875, Product Code DQD)

Classification: Class II

Predicate Devices: BL Healthcare Remote Care Management System  
BL Healthcare, Inc.  
K051470

Telecare D.R.  
HealthCare Vision, Inc.  
K033133

CareStation 126S Videophone  
Motion Media Technology, Inc.  
K031863

Device Description: The Remote Presence Robotic System is a mobile, robotic telecommunications platform that enables real-time videoconferencing. The Remote Presence Robotic System consists of a ControlStation (a desktop or laptop computer) and the RP-7 mobile robot, which is most often linked via broadband Internet and an 802.11 wireless network. The Robot and ControlStation are each equipped with cameras, displays, microphones and speakers, allowing two-way audio-video communication. Additionally, the ControlStation is equipped with a joystick that the operator uses to control the movement of the Robot in the remote location. As a result, the user can move through a remote facility and engage in conversations as if physically present while seated at a ControlStation in a remote facility with broadband Internet access.

As an option, the Remote Presence Robotic System includes an integrated electronic stethoscope. The stethoscope is a FDA-cleared device which is used for the same purpose for which it received 510(k) clearance, i.e., to transmit auscultation sounds from a patient at one location to a clinic at a different location. The System provides a channel for the digital data that the stethoscope transmits.

**Intended Use:** The Remote Presence Robotic System is a communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence Robotic also can be used in conjunction with 510(k)-cleared devices that transmit patient biometric data including vital signs information. The Remote Presence Robotic System transmits and receives information over high speed connection between patients and health professional, and is intended to be used in a hospital or clinic environment. Clinical judgment and experience are required to review and interpret the information transmitted.

**Technological Characteristics:** Like the predicate devices, the Remote Presence Robotic System provides a real-time link between the patient and the healthcare professional. This link occurs over broadband Internet and includes real-time audio and video to facilitate communication between the patient, patient-side healthcare professionals, and remote healthcare professionals. Also like the predicate devices, the Remote Presence Robotic System transfers data from 510(k)-cleared devices between the patient and the healthcare professional. Like the predicate devices, the devices are not controlled or manipulated through the Remote Presence Robotic System, and consequently, no additional risk is presented.

Unlike the predicate devices, the Remote Presence Robotic System provides mobility to the physician by allowing the physician to control the movement of the mobile robotic platform within the healthcare facility. The real-time audio video link allows the driver to see and hear effectively within the remote environment.

**Performance Data:** Redundant safeguards are designed into the Remote Presence Robotic System to address risks associated with the mobility of the robotic platform. The effectiveness of these measures, and the videoconferencing link were demonstrated by the validation testing performed on the system. The communication channel used by the electronic stethoscope was also proven effective by independent tests.

**Conclusions:** The performance data discussed in this 510(k) application demonstrate that the Remote Presence Robotic System is as safe and effective, and performs as well as or better than the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**APR 11 2008**

InTouch Technologies Inc.  
c/o Mr. Bill Stout  
Director of Operations  
90 Castilian Drive, Suite 200  
Goleta, CA 93117

Re: K073710  
Trade Name: Remote Presence Robotic System, Model RP-7  
Regulation Number: 21 CFR 870.2910  
Regulation Name: Transmitters And Receivers, Physiological Signal, Radiofrequency  
Regulatory Class: Class II (two)  
Product Codes: DRG  
Date: February 28, 2008  
Received: February 29, 2008

Dear Mr. Stout:

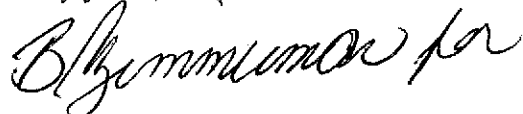
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman" followed by a stylized flourish.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**ATTACHMENT 1**  
**Indications for Use**510(k) Number      Not assigned.  
(if known):

Device Name:      Remote Presence Robotic System

Indications for Use: The Remote Presence Robotic System is a communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence Robotic also can be used in conjunction with 510(k)-cleared devices that transmit patient biometric data including vital signs information. The Remote Presence Robotic System transmits and receives information over high speed connection between patients and health professional, and is intended to be used in a hospital or clinic environment. Clinical judgment and experience are required to review and interpret the information transmitted.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Gammeter  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K073710